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Segel

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(54) **ORTHOTIC FOR USE IN FOOTWEAR**

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(51) **Int. Cl.**

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A43B 7/16	(2006.01)
A43B 7/22	(2006.01)
A43B 13/18	(2006.01)
A43B 17/02	(2006.01)
A43B 13/14	(2006.01)

(52) **U.S. Cl.**
CPC ***A43B 13/183*** (2013.01); ***A43B 7/16*** (2013.01); ***A43B 17/02*** (2013.01); *A43B 13/143* (2013.01); *A43B 13/148* (2013.01)

(58) **Field of Classification Search**
CPC .. A43B 13/143; A43B 13/145; A43B 13/146; A43B 13/148; A43B 7/1465; A43B 7/1415; A43B 7/22
USPC 36/43, 44, 71, 140, 150, 154, 172, 36/161–165
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,992,853	A *	2/1935	Barrett	36/162
2,096,500	A *	10/1937	McCahan et al.	36/144
2,207,833	A *	7/1940	Stark	36/140
2,311,925	A *	2/1943	Boos	36/163
2,401,514	A	6/1946	Scholl	
2,441,891	A *	5/1948	Lucey et al.	12/142 N
2,518,033	A *	8/1950	Lucas	36/163
3,859,740	A	1/1975	Kemp	
4,517,981	A	5/1985	Santopietro et al.	
4,686,993	A	8/1987	Grumbine	
4,760,655	A *	8/1988	Mauch	36/44
4,823,420	A	4/1989	Bartneck	
4,910,884	A *	3/1990	Lindh et al.	36/28
5,881,478	A *	3/1999	McMahon et al.	36/144
6,098,319	A *	8/2000	Epstein	36/159
6,247,250	B1	6/2001	Hauser	
6,543,158	B2	4/2003	Dieckhaus	
6,782,643	B2 *	8/2004	Brown	36/144
6,817,115	B2	11/2004	Polifroni	
7,017,218	B2	3/2006	Nguyen	
7,334,351	B2 *	2/2008	Hann	36/27
7,913,429	B1 *	3/2011	Wert	36/159
2002/0050080	A1	5/2002	Vasyli	

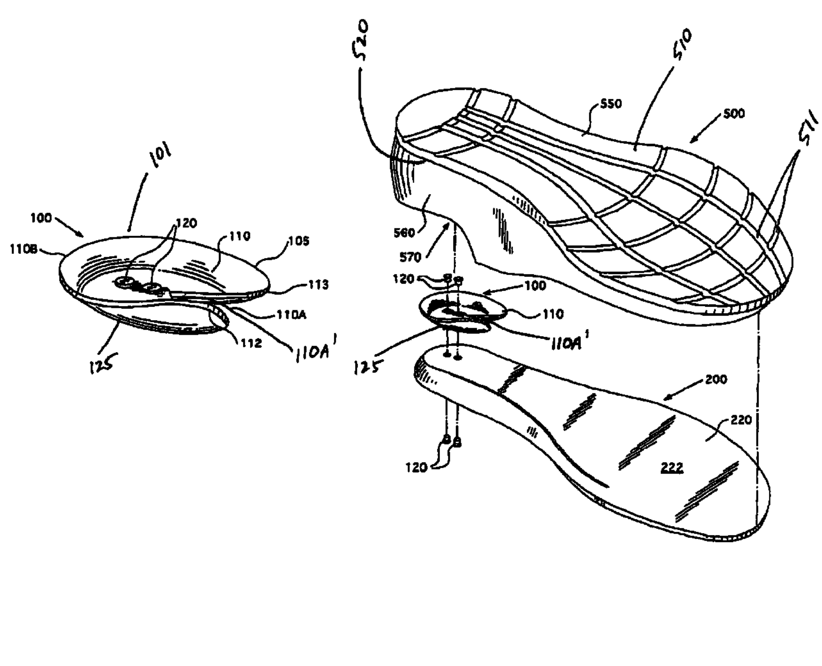
* cited by examiner

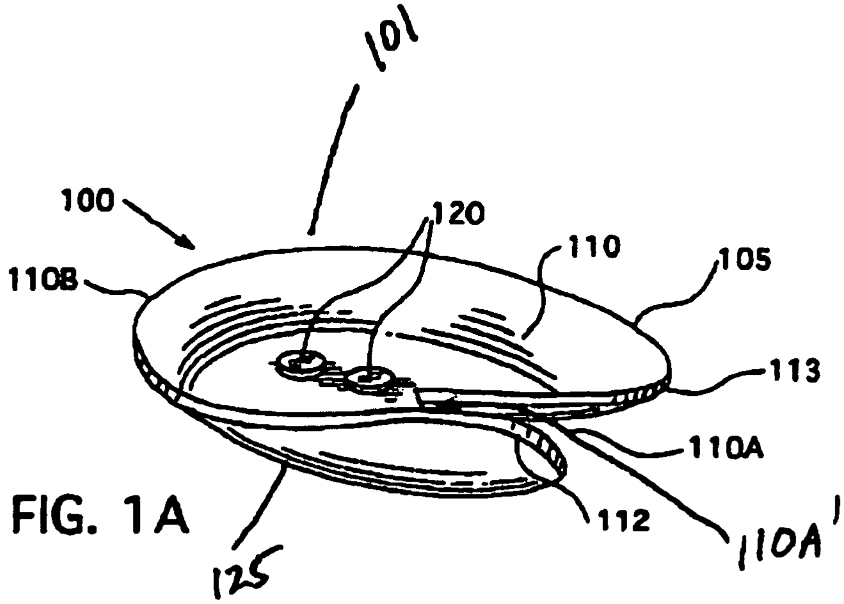
Primary Examiner — Jila M Mohandesi

(57) **ABSTRACT**

An orthotic is disclosed. The orthotic has a convex element that has a periphery. The convex element is positioned in a plane. The periphery is structured and arranged to deform into a gap in at least of a horizontal, a vertical, or a lateral direction relative to the plane. The convex element is structured and arranged for placement between a plantar surface of a foot and a second surface. The gap is defined by a top surface of the convex element and a bottom surface of the foot or a bottom surface of a body of an insert. The periphery of the convex element is structured and arranged to deform into the gap as a force is applied to the body and to rebound as the force dissipates.

1 Claim, 8 Drawing Sheets




101
100
120
110
105
110B
113
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112
110A'
125

FIG. 1A

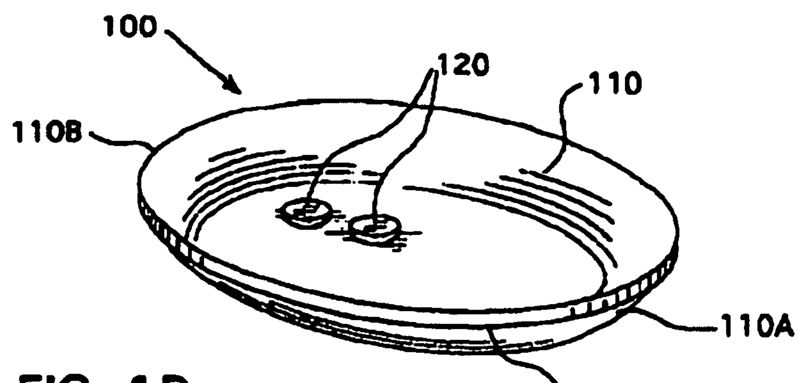
100
120
110
110B
110A
105

FIG. 1B

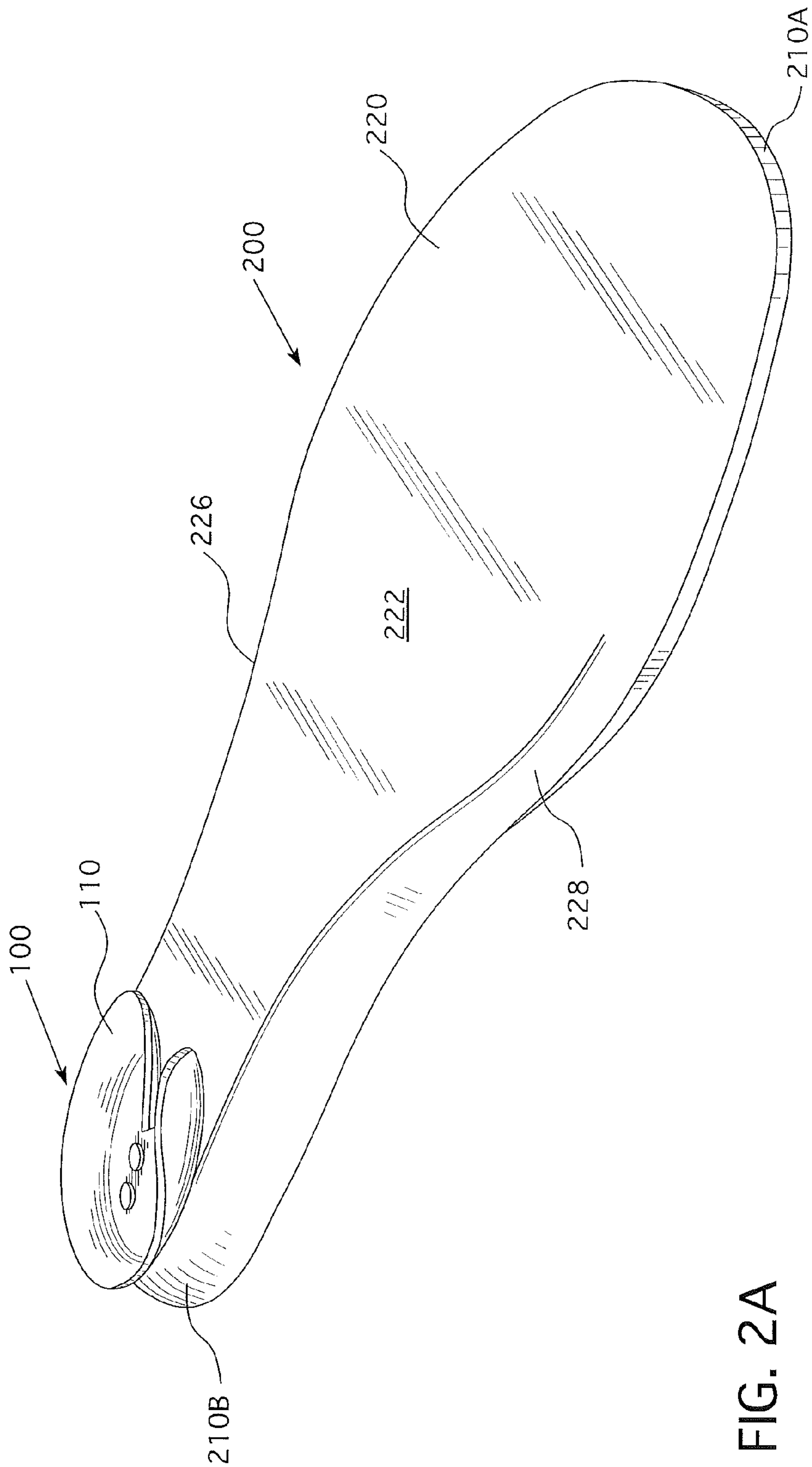

FIG. 2A

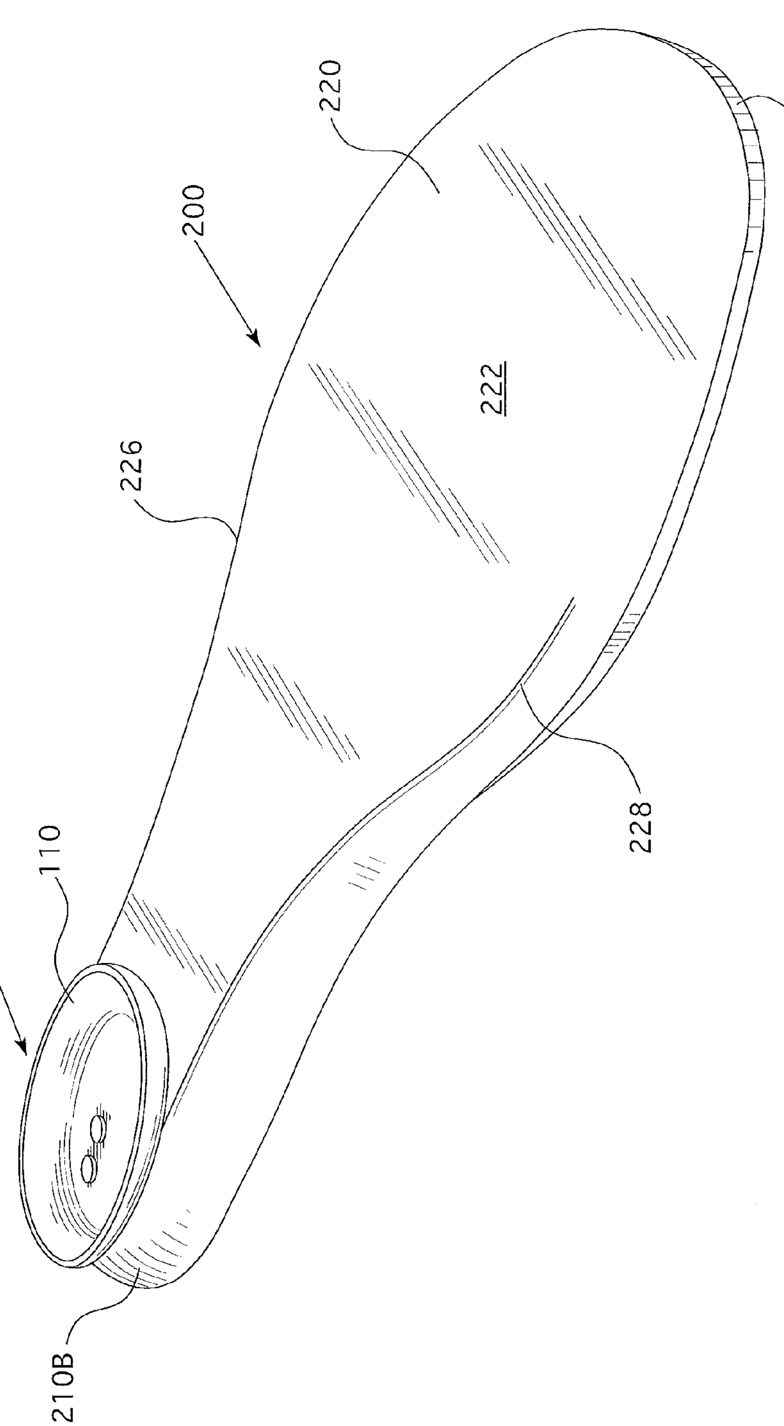

FIG. 2B

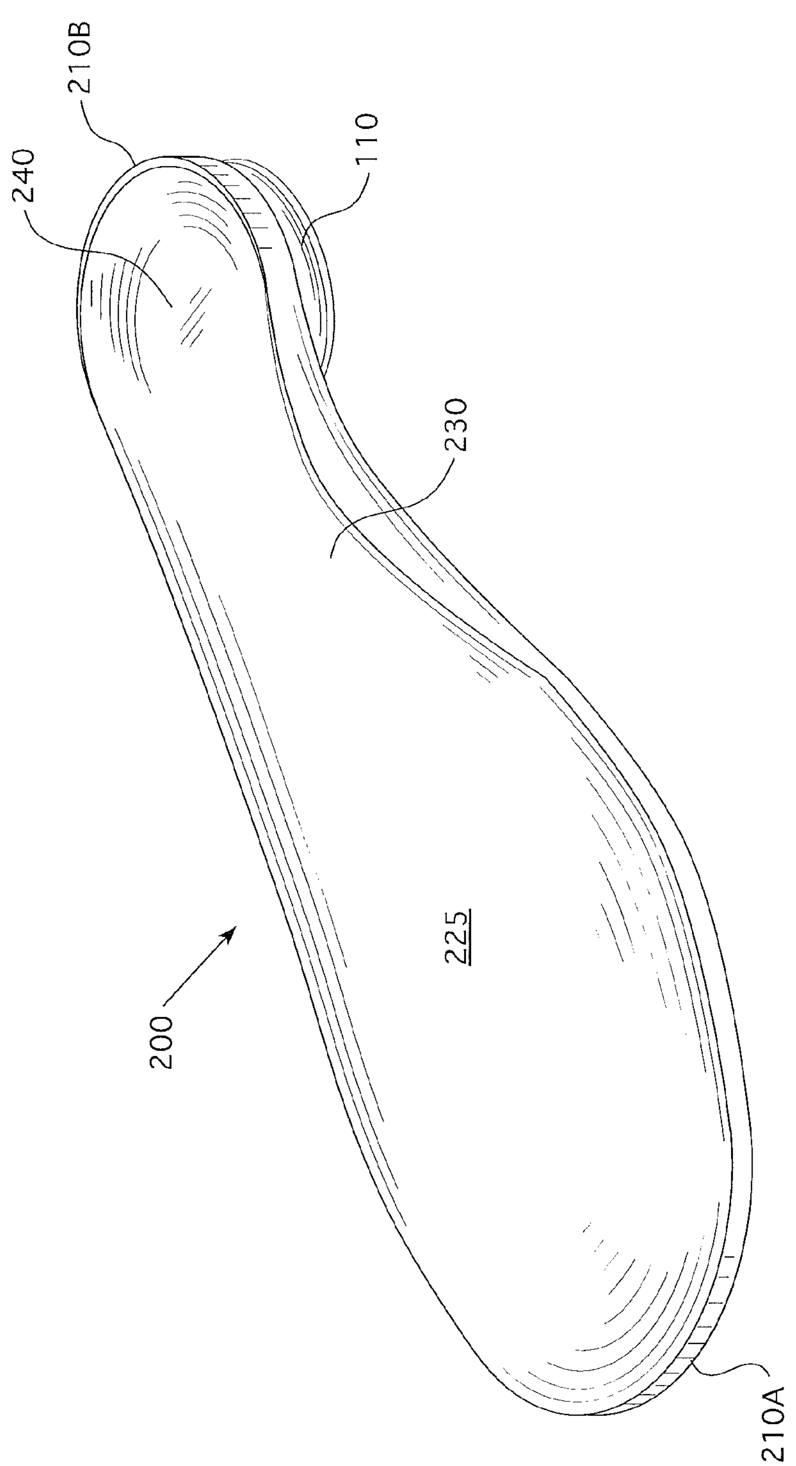

FIG. 3

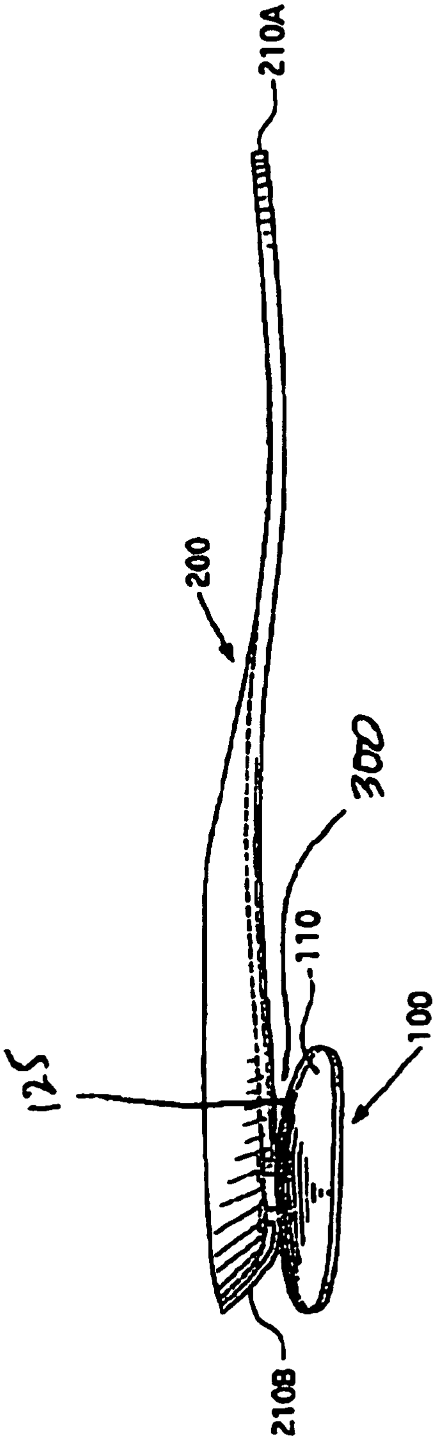

FIG. 4

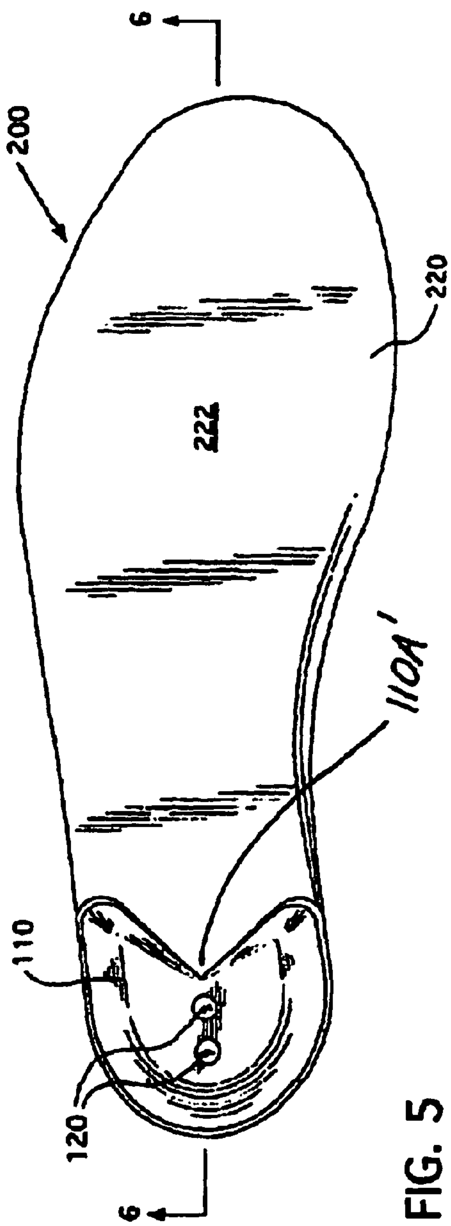

FIG. 5

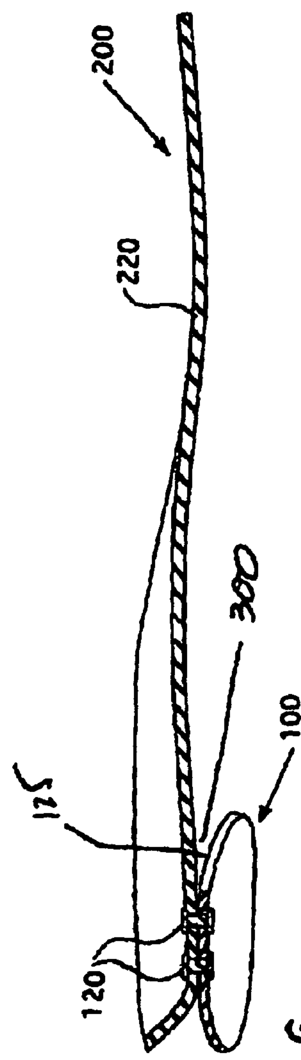

FIG. 6

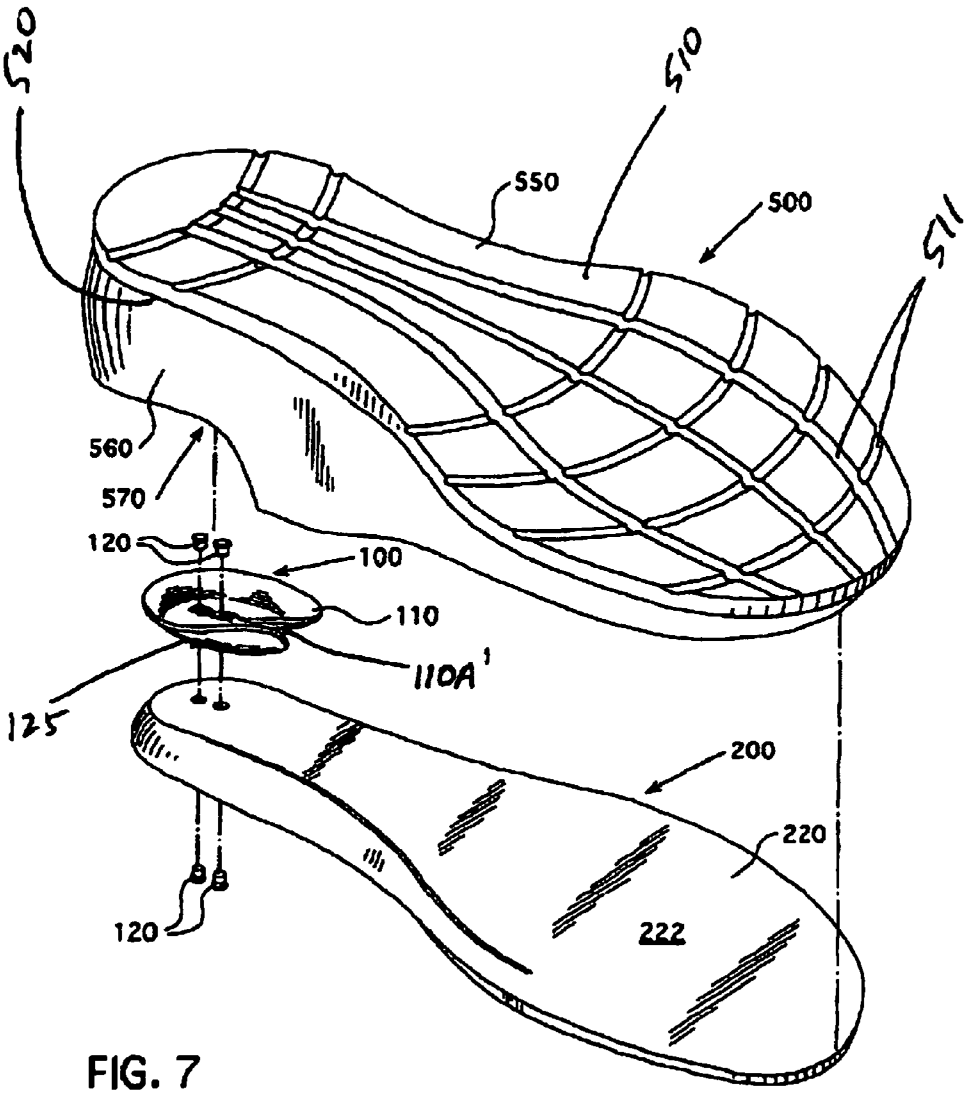

FIG. 7

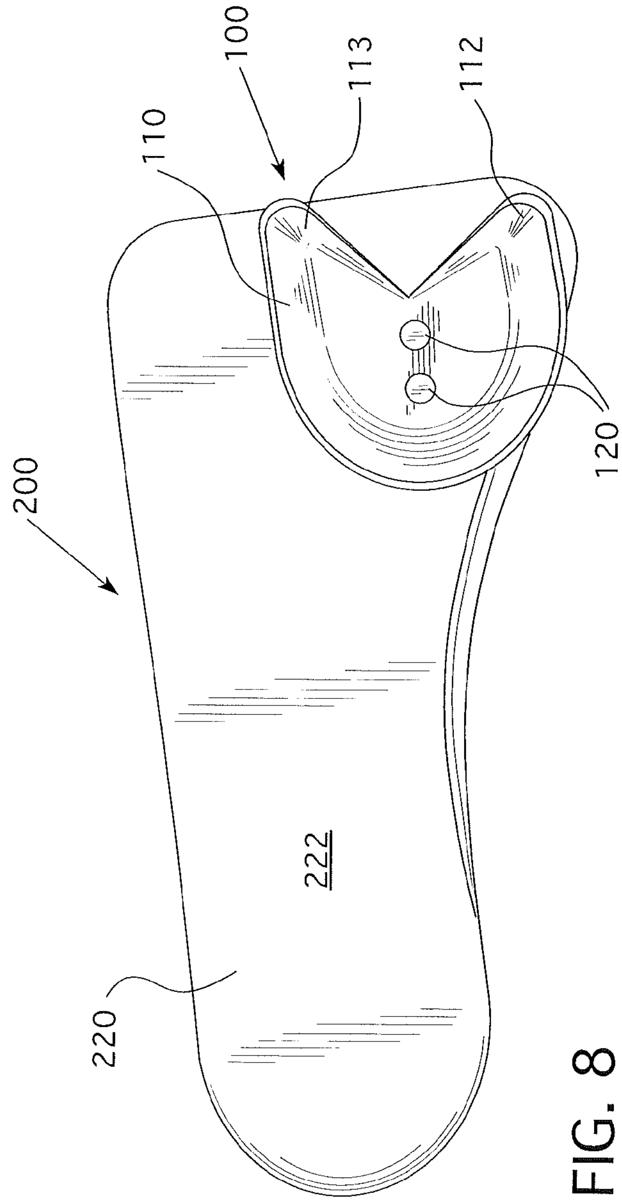

FIG. 8

ORTHOTIC FOR USE IN FOOTWEAR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 12/321,355, filed on Jan. 12, 2009, and incorporated herein by reference.

BACKGROUND

In a gait cycle, the foot optimally goes through pronation and supination. When either of these tri-plane motions is made in excess, the foot is subject to biomechanical maladies with these excess deviations from its neutral position. Additionally, the foot in stance is subject to ground force reaction which often is the cause of foot deformity. However, conventional orthotics fail to actively manage motion in the horizontal, vertical, and lateral planes of motion during gait or in stance and therefore do not efficiently adjust to ground forces, stabilize the foot, or assist in propulsion during propulsion.

SUMMARY

In an embodiment, an orthotic is disclosed. The orthotic has a convex element that has a periphery. The convex element is positioned in a plane. The periphery is structured and arranged to deform into a gap in at least of a horizontal, a vertical, or a lateral direction relative to the plane. The convex element is structured and arranged for placement between a plantar surface of a foot and a second surface. The gap is defined by a top surface of the convex element and a bottom surface of the foot or a bottom surface of a body of an insert.

In another embodiment, an insert adapted to be used in footwear is disclosed. The insert has a body having a proximal end, a distal end, a top surface shaped to receive a plantar surface of a foot, a bottom surface, and a raised arch positioned on a medial side. A concave heel portion is formed in the top surface of the body at the proximal end of the body and is shaped to receive a heel of the foot. An orthotic having a convex element having a periphery is attached to the bottom surface of the body at the proximal end of the body substantially below the concave heel portion. There is a gap defined by the bottom surface of the body and a top surface of the convex element. The periphery of the convex element is structured and arranged to deform into the gap as a force is applied to the body and to rebound as the force dissipates. In an embodiment, the convex element has a parabolic proximal end and a cut-out at a distal end that forms medial and lateral members, wherein the medial and lateral members are structured and arranged to deform into the gap as the force is applied to the body and to rebound as the force dissipates.

In another embodiment, an insert adapted to be used in footwear is disclosed. The insert has a body having a proximal end, a distal end, a top surface shaped to receive a plantar surface of a foot, a bottom surface, and a raised arch positioned on a medial side. A concave heel portion formed in the top surface at the proximal end is shaped to receive a heel of the foot. An orthotic having a convex element having a periphery is attached to a bottom surface of the body at the distal end of the body proximal to the raised arch. A gap is defined by the bottom surface of the body and a top surface of the convex element. The periphery of the convex element is structured and arranged to deform into the gap as a force is applied to the body and to rebound as the force dissipates. In an embodiment, the convex element has a parabolic proximal end and a cut-out at a distal end that forms medial and lateral members, wherein the medial and lateral members are structured and arranged to deform into the gap as the force is applied to the body and to rebound as the force dissipates.

In another embodiment, an article of footwear is disclosed. The footwear has an upper having an opening that extends to an interior cavity that is structured and arranged to receive a foot. A sole structure is secured to the upper and is positioned below the opening. The sole structure has a proximal end, a distal end, a top surface positioned within the opening, and an opposite bottom surface. The footwear has an insert structured and arranged for positioning within the interior cavity. The insert has a body having a proximal end, a distal end, a top surface shaped to receive a plantar surface of the foot, a bottom surface structured and arranged to oppose the top surface of the sole structure, and a raised arch positioned on a medial side. There is a concave heel portion formed in the top surface of the body of the insert at the proximal end that is shaped to receive a heel of the foot. An orthotic having a convex element having a periphery is attached to the bottom surface of the body of the insert. A gap is defined by the bottom surface of the body and a top surface of the convex element. The periphery of the convex element is structured and arranged to deform into the gap as a force is applied to the body and to rebound as the force dissipates.

Other objects, features, aspects and advantages of the orthotic insert will become better understood or apparent from the following detailed description, drawings, and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A illustrates a top isometric view of an embodiment of an orthotic.

FIG. **1**B illustrates a top isometric view of another embodiment of an orthotic.

FIG. **2**A illustrates a bottom isometric view of the orthotic illustrated in FIG. **1**A attached to an embodiment of an insert for use in footwear.

FIG. **2**B illustrates a bottom isometric view of the orthotic illustrated in FIG. **1**B attached to an embodiment of an insert for use in footwear.

FIG. **3** illustrates a top isometric view of the orthotic attached to the insert illustrated in FIG. **2**A.

FIG. **4** illustrates a side view of the orthotic attached to the insert illustrated in FIG. **2**A.

FIG. **5** illustrates a bottom view of the orthotic attached to the insert illustrated in FIG. **2**A.

FIG. **6** illustrates a cross-sectional view of the orthotic attached to the insert illustrated in FIG. **2**A and taken along line **6**-**6** in FIG. **5**.

FIG. **7** illustrates an exploded detail view of the orthotic and the insert illustrated in FIG. **2**A in combination with a shoe.

FIG. **8** illustrates a bottom view of the orthotic illustrated in FIG. **1**A attached to another embodiment of an insert for use in footwear.

DETAILED DESCRIPTION

As shown generally in the figures, embodiments of an orthotic device **100** are disclosed. In certain embodiments, in use the orthotic **100** may be inserted into footwear **500** and worn between the plantar aspect of a foot and a top surface of a shoe or in-shoe appliance such as an insole, foot bed, or heel cup, referred to collectively herein as a removable insole or insert **200**, described below. In certain embodiments, the orthotic **100** may directly contact the plantar surface of the foot in use. In certain embodiments, the orthotic **100** and the body of the insert may be unitary.

The orthotic **100** is configured to assist the musculoskeletal system in the responsive management of a triplane motion at the foot and ankle by repositioning the foot and providing motion control while dynamically absorbing shock. The deformable periphery of the orthotic provided graded adaptation to uneven surfaces and measured management of ground force reaction. The orthotic **100** is active at the stance phase, early in the gait cycle, and side to side motion, and rebounds to its original position later in the gait cycle, which stabilizes and propels the foot actively forward and provides for improved timing and foot mechanics compared to other orthotics.

As illustrated generally in the figures and particularly in FIGS. **1**A and **1**B, the orthotic **100** has a convex element **110** positioned in a plane. The periphery **105** of the convex element **110** is deformable and is structured and arranged to deform and rebound in use, as described in greater detail below. In an embodiment illustrated in FIG. **1**A, the orthotic **100** has a parabolic proximal end **110**A with a cut-out **110**A' and a parabolic distal end **110**B. The cut-out forms a medial member **112** and a lateral member **113**. Each member **112**, **113** has a periphery that is deformable and is structured and arranged to deform and rebound in use, as described in greater detail below. In another embodiment illustrated in FIG. **1**B, the orthotic **100** has a parabolic proximal end **110**A and a parabolic distal end **110**B. In certain embodiments, the orthotic **100** has fasteners **120** that fasten or attach the orthotic to a bottom surface **222** of the body **220** of the insert **200**, described below. In certain embodiments, the convex element **110** may be formed of an injected molded plastic, wood, fibers, composites, metals, polymers, graphite, or the like.

As illustrated in FIGS. **2** through **8**, in certain embodiments, the orthotic device **100** may be attached to a removable insole or insert **200**. The removable insole or insert **200** has a body **220** and a concave heel portion **230**. The orthotic device **100** is positioned adjacent to the removable insole or insert **200** below a bottom surface of the body **220**.

As illustrated in FIGS. **2** through **8**, the removable insole or insert **200** has a body **220**. The body **220** has a proximal end **210**A and a distal end **210**B, a top surface **225** and a bottom surface **222**, and a medial side **226** and a lateral side **228**. The top surface **225** is shaped to receive a plantar surface of a foot and may substantially contour to a shape of the foot. A raised arch **230** is positioned on the medial side **226** of the body **220**. In the embodiments illustrated in FIGS. **2** through **7**, the body **220** may be configured to extend substantially over a width and a length of a foot, although in other embodiments such as the one illustrated in FIG. **8**, the body **220** may be configured to extend over only a portion of the length of the foot. In embodiments such as the one illustrated in FIGS. **2** through **7**, the distal end **210**B may be configured to be positioned about 1 cm to about 12 cm proximal to the metatarsal heads. In certain embodiments, the distal end **210**B may be configured to end proximal to the metatarsal heads. In embodiments such as the one illustrated in FIG. **8**, the proximal end **210**A is configured to begin substantially near the longitudinal arch and to extend, in certain embodiments, up to about 10 mm proximal to the metatarsal heads in order to manage forefoot motion at the transverse arch during the terminal phase of gait. In an embodiment, the body **220** may be substantially rigid, resiliently rigid, or accommodative to movement. In an embodiment, the body **220** may be formed of an injected molded plastic, wood, fibers, composites, metals, polymers, graphite, and the like.

As illustrated in FIG. **3**, the insert **200** has a concave heel portion **240** formed in the top surface **225** of the body **220** at the proximal end **210**A of the body **220**. In embodiments, the concave heel portion **240** may be shaped to receive a heel of the foot. In embodiments, the concave heel portion **240** may have a depth that ranges from about 4 mm to about 18 mm.

As illustrated in FIG. **4**, a gap **300** is defined by the bottom surface **222** of the body **220** of the insert **200** and a top surface **125** of the convex element **110** of the orthotic **100**. The periphery **105** of the convex element **110** is structured and arranged to deform into the gap **300** as a force is applied to the body **220** and to rebound as the force dissipates. The orthotic **100** provides a graded adaptation to uneven surfaces and a measured management of ground force reaction. The periphery **105** of the convex element **110** is structured and arranged to rebound as the force dissipates, thereby resupinating the foot for early stability and efficient propulsive phase of gait. In use, the convex element **110** functions as a shock absorber and provides medial and lateral motion control, energy return, proprioceptive cuing, and dynamic resupination of the foot.

The orthotic **100** may be positioned anywhere along the body **220** of the insert **200**. In an embodiment illustrated in FIGS. **2** to **7**, the orthotic **100** may be positioned at the proximal end **210**A of the body **220** substantially below the concave heel portion **240** of the body **220**. In an embodiment illustrated in FIG. **8**, the convex element **110** may be positioned at the distal end **210**B of the body **220** proximal to the raised arch **230**.

In another embodiment, the orthotic **100** may be adapted for use in footwear **500**. An embodiment of an article of footwear **500** in combination with the orthotic **100** and an insert **200** is illustrated in FIG. **7**. The footwear **500** may have an outsole **550** and an upper **560**. The outsole **550** having an outer surface **510** for engaging the ground when the footwear is being used and an opposite inner surface **520**, the outer surface **510** further includes threads **511** for providing traction. The upper **560** has an opening **570**, and the upper **560** is attached to the outsole **550**, wherein the upper in combination with the outsole **550** and the opposite inner surface **520** form an interior cavity **580**, the opening **570** extends to the interior cavity **580** that is configured to receive a foot of a user. The outsole **550** is secured to the upper **560** and is positioned below the opening **570**. The outsole **550** has proximal and distal ends **550**A, **550**B, a top surface **525** positioned within the interior cavity **580** of the upper **560**, and an opposite bottom surface **522**. In use, the orthotic device **100** may be positioned in the interior cavity **580** of the footwear **500** on the top surface **525** of the outsole **550**. Optionally, the orthotic device **100** may be attached to a removable insole **200**. The removable insole **200** is inserted and positioned entirely within the interior cavity **580**, the removable insole **200** has a body **220**, the body **220** has a proximal end **210**A, a distal end **210**B, a top surface **225**, a bottom surface **222**, a medial side **226** and a lateral side **228**, the top surface **225** is shaped for receiving a plantar surface of the foot and substantially contoured to a shape of the foot, a raised arch **230** is positioned on the medial side **226** of the body **220**, the removable insole **200** further includes a concave heel portion **240** formed in the top surface **225** at the proximal end **210**A of the body **220**.

Illustrating the invention are the following examples that are not to be considered as limiting the invention to their details.

EXAMPLE

Twenty three (23) subjects were tested. Each subject was without acute or inhibiting symptoms or pathologies. Each subject received an appropriate size commercially available orthotic (designated herein as "L") and an orthotic such as the one illustrated in FIG. 2A, having the convex element attached to the bottom surface substantially below the concave heel portion (designated herein as "D"). The orthotics (L and D) were made of either a composite material (designated herein as "C") or a plastic material (designated herein as "P").

Testing was performed on Noraxon's FDM-T treadmill (force distribution measurement treadmill) for stance and gait analysis. The FDM-T treadmill controls speed and the walking surface and also measures temporal and special gait parameters, kinetics, pressure and ground reaction forces complete and segmented.

Each subject completed a questionnaire that included questions regarding medical history, preexisting conditions or symptoms, and level of comfort with walking on a treadmill. Each subject was positioned on the FDM-T treadmill, the treadmill was calibrated and started. For each subject, the following protocol was followed:

(1) Wearing walking shoe without any orthotic inserts (designated herein as "R"):

a. Walk on treadmill for 60 seconds at 1.5 kilometers per hour. No data were recorded during this time period.
b. Then, record data while subject walks for an additional 30 seconds at 1.5 kilometers per hour (Dynamic Gait I—R).
c. Increase speed of treadmill to subject's speed of choice and walk on treadmill for 60 seconds. No data were recorded during this time period.
d. Then, record data while subject walks for an additional 30 seconds at the speed selected in step c above (Dynamic Gait II—R).

(2) Wearing walking shoes with an "L" orthotic insert made of either C or P:

a. Walk on treadmill for 60 seconds at 1.5 kilometers per hour. No data were recorded during this time period.
b. Then, record data while subject walks for an additional 30 seconds at 1.5 kilometers per hour (Dynamic Gait I—LC or LP).
c. Increase speed of treadmill to subject's speed of choice and walk on treadmill for 60 seconds. No data were recorded during this time period.
d. Then, record data while subject walks for an additional 30 seconds at the speed selected in step c above (Dynamic Gait II—LC or LP).
e. Then, record data while subject steps laterally (Lateral Side-Step—LC or LP).

(3) Wearing walking shoes with a "D" orthotic insert made of either C or P:

a. Walk on treadmill for 60 seconds at 1.5 kilometers per hour. No data were recorded during this time period.
b. Then, record data while subject walks for an additional 30 seconds at 1.5 kilometers per hour (Dynamic Gait I—DC or DP).
c. Increase speed of treadmill to subject's speed of choice and walk on treadmill for 60 seconds. No data were recorded during this time period.
d. Then, record data while subject walks for an additional 30 seconds at the speed selected in step c above (Dynamic Gait II—DC or DP).
e. Then, record data while subject steps laterally (Lateral Side-Step—DC or DP).

In each subject, data recorded with the D orthotic inserted into the shoes were compared to data recorded while the subject had the L orthotic inserted into the shoes. Data over subjects were averaged and are summarized below.

TABLE 1

Direct Comparisons Between D and L Orthotic Inserts

Measurement	Increase/Decrease (mm) Left Foot	Increase/Decrease (mm) Right Foot	Increase/Decrease (mm) Anterior, Posterior, Lateral
Average gait line	+5.17	+4.35	NA NA
Average deviation in gait line length	−2.1	−0.57	NA
Average single support line	+3.9	+2.09	NA
Average deviation in single support line	−0.87	−0.22	NA
Average anterior/posterior position	NA	NA	+0.13
Average anterior/posterior variation	NA	NA	−0.22
Average lateral symmetry	NA	NA	+1.83
Average lateral symmetry variation	NA	NA	−1.57

TABLE 2

Direct Comparisons Between D and L Orthotic Inserts

Measurement	Increase/Decrease Left Side	Increase/Decrease Right Side	Increase/Decrease
Average foot abduction	−0.19°	−0.4°	
Average step width			−0.31 cm
Average step length	+0.73 cm	+1.34 cm	
Average step time	+0.01 sec	+0.02 sec	
Average time in stance	+0.62%	0.49%	
Average loading response	+0.68%	+0.40%	
Average single support	−0.51%	−0.58%	
Average pre-swing	+0.5%	+0.61%	
Average swing phase	−0.62%	−0.49%	
Average total double support			+1.1%
Average stride length			+2.00 cm
Average stride time			+0.03 sec
Cadence			−1.82 steps/min

These results indicate that stability and lateral movement are controlled by the orthotic insert having the convex element (D) so that there is less variability of center of pressure in all directions. Energy is stored and returned more efficiently so that strides are longer, more neutral in position, and loading responses are faster. Finally, resupination is faster, and preparation for propulsion to the next contact is faster.

During lateral stepping, an average increase of about 8 frames (8 ms) in lateral shift or pronation from a lateral supinated landing during the side step was measured in the D insert compared to the L insert. These data indicate that there was an increase in time to recenter after the supinated transversal motion.

When subjects used the D insert compared to the L insert, the center of pressure of a subject stepping laterally covered a smaller distance, indicating that even in the transversal plane, the D insert manages lateral motion and corrects the foot's position more effectively.

Additionally, when subjects wore the D insert compared to the L insert, there was a decrease in path length of the center of pressure, indicating that there was a smaller change in center of pressure with the D insert.

Finally, the average velocity (mm/sec) increased by 5.73 mm/sec when the subjects wore the D insert compared to the L insert.

While the foregoing has been set forth in considerable detail, it is to be understood that the drawings and detailed embodiments are presented for elucidation and not limitation. Design variations, especially in matters of shape, size and arrangements of parts may be made but are within the principles described herein. Those skilled in the art will realize that such changes or modifications of the invention or combinations of elements, variations, equivalents or improvements therein are still within the scope of the orthotic insert as defined in the appended claims.

I claim:

1. A footwear (**500**) used in combination with an orthotic device (**100**), the footwear comprising:

an outsole (**550**) having an outer surface (**510**) for engaging the ground when the footwear is being used and an opposite inner surface (**520**), the outer surface (**510**) further includes threads (**511**) for providing traction;

an upper (**560**) having an opening (**570**), the upper (**560**) is attached to the outsole (**550**), wherein the upper in combination with the outsole (**550**) and the opposite inner surface (**520**) form an interior cavity (**580**), the opening (**570**) extends to the interior cavity (**580**) that is configured to receive a foot of a user;

a removable insole (**200**) inserted and positioned entirely within the interior cavity (**580**), the removable insole (**200**) has a body (**220**), the body (**220**) has a proximal end (**210**A), a distal end (**210**B), a top surface (**225**), a bottom surface (**222**), a medial side (**226**) and a lateral side (**228**), the top surface (**225**) is shaped for receiving a plantar surface of the foot and substantially contoured to a shape of the foot, a raised arch (**230**) is positioned on the medial side (**226**) of the body (**220**), the removable insole (**200**) further includes a concave heel portion (**240**) formed in the top surface (**225**) at the proximal end (**210**A) of the body (**220**);

the orthotic device (**100**) is fastened to the bottom surface (**222**) of the body (**220**) of the removable insole (**200**), using a pair of fasteners (**120**), at the proximal end (**210**A) below the concave heel portion (**240**) of the body (**220**), the orthotic device (**100**) and the removable insole (**200**) are inserted and positioned entirely within the interior cavity (**580**) such that during use, the orthotic device (**100**) comes into direct contact with the opposite inner surface (**520**) of the outsole (**550**), wherein the orthotic device (**100**) provides a graded adaptation to uneven surfaces and a measured management of ground force reaction,

the orthotic device (**100**) further consisting of: a convex element (**110**), a top surface (**125**) of the convex element (**110**), a periphery (**105**) of the convex element (**110**) structured and arranged to deform and rebound during use, a parabolic proximal end (**110**A) with a cut-out (**110**A') and a parabolic distal end (**110**B), the cut-out (**110**A') forms a medial member (**112**) and a lateral member (**113**), wherein each of the medial (**112**) and lateral (**113**) members structured and arranged to deform and rebound in use, wherein the convex element (**110**) functions as a shock absorber and provides medial and lateral motion control, energy return, proprioceptive cuing, and dynamic resupination of the foot in use; and

a gap (**300**) is defined by the bottom surface (**222**) of the body (**220**) of the removable insole (**200**) and the top surface (**125**) of the convex element (**110**) such that during use, the periphery (**105**) of the convex element (**110**) is deformed into the gap (**300**) as a force is applied to the body (**220**) of the removable insole (**200**) and to rebound as the force dissipates.

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